UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Novartis and Par Antitrust Litigation	**1:18-cv-04361-AKH**
This Document Relates To: All Actions	

MEMORANDUM OF LAW IN SUPPORT OF NOVARTIS DEFENDANTS' MOTION TO COMPEL OPTUMRX, INC.'S PRODUCTION OF DATA RESPONSIVE TO SUBPOENA

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Novartis Pharmaceuticals Corporation and Novartis AG (together, "Novartis") submit this motion to compel OptumRx, Inc. ("Optum") pursuant to Fed. R. Civ. P. 37(a) and 45(d)(2)(B)(i). Novartis respectfully requests that the Court compel Optum to produce its claims data and rebate data for the anti-hypertensive medication Exforge and its generic versions in response to Novartis's subpoena *duces tecum* served on October 11, 2019.[1] The data sought is relevant and non-privileged, and whatever the burden in producing it, it is commensurate with the damages that the members of the proposed "End-Payor Plaintiff" ("EPP") class in this case—who used Optum as their pharmacy benefits manager—are seeking from Defendants, Novartis and Par Pharmaceutical, Inc. ("Par").

I. PRELIMINARY STATEMENT

The EPPs in this case allegedly reimbursed pharmacies for their insureds' purchases of Exforge and its generic equivalents. EPPs claim that they paid inflated prices for these products due to a license agreement between Novartis and Par. *See* ECF No. 40. The data this motion seeks relate to those transactions, and will allow Novartis to determine the effective prices that EPPs actually paid for Exforge and its generic equivalents. To assess EPPs' damages claims and eligibility for class certification, Novartis is entitled to take such discovery, including from non-parties like Optum.

Optum has refused without justification to produce certain categories of data requested. Over the last year, Novartis has met and conferred numerous times with Optum requesting that it provide this information, but Optum has refused, forcing Novartis to make this motion.[2]

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[1] Optum, during a phone call with Novartis counsel on December 18, 2020, agreed that this Court was the proper venue for this motion.

[2] Novartis files herewith the Declaration of Julie A. North ("North Decl.") and accompanying exhibits in support of this motion.

II. FACTUAL BACKGROUND

Optum is a pharmacy benefits manager ("PBM"), which manages prescription medication benefits on behalf of insurers, health benefit funds and other third-party payors that are included in the putative class of EPPs. PBMs play a central role in pharmaceutical transactions, including by negotiating prices for medications on behalf of their EPP clients with pharmacies (which PBMs reimburse for prescribed medications) and pharmaceutical manufacturers. In the course of those negotiations, PBMs often secure rebates and discounts on those prices, frequently passing along the savings to their clients. *See, e.g.*, *In re Express Scripts/Anthem ERISA Litig.*, 285 F. Supp. 3d 655, 663 (S.D.N.Y. 2018) (describing the role of PBMs in pharmaceutical transactions). As the Congressional Budget Office ("CBO") has explained, "PBMs play a key role in negotiating the final price that manufacturers and pharmacies receive on a prescription drug sale." CONG. BUDGET OFF., PRESCRIPTION DRUG PRICING IN THE PRIVATE SECTOR, PAPER PUB. NO. 2703, at 10 (2007), *available at* https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf.[3]

Thus, the actual prices paid by the EPPs for medications like Exforge are determined, at least in part, by the amount of rebates and discounts they receive from PBMs like Optum. Data reflecting effective prices paid by the members of the broad putative class of EPPs is only available, as a practical matter, from PBMs like Optum, which enter into contracts with many members of the putative class. The two named EPPs in this action have only produced data reflecting the effective prices they paid under their own PBM contracts for Exforge and generic Exforge. But Novartis seeks class-wide data to assess potential damages and whether the calculation of the alleged

[3] For the Court's convenience, to illustrate the role that PBMs play in the pharmaceutical purchasing process, we have annotated a CBO diagram in North Decl. Ex. J to reflect the parties involved here.

overcharges paid by specific EPPs demands an individualized inquiry, such that class certification may be inappropriate. To otherwise obtain similar purchase data for the entire putative EPP class, Novartis would have to subpoena each individual entity in the putative class. Accordingly, to more efficiently obtain data pertaining to purchases of Exforge and generic Exforge by a substantial portion of the EPP class, Novartis served targeted subpoenas on the three largest PBMs, including Optum.[4] This motion seeks to compel production of claims data and rebate data in response to Request No. 1 of the subpoena served on Optum, which reads as follows:

Request No. 1: "Concerning Exforge and Generic Exforge,[5] [Optum's] Transaction Data; [] Discount Data, [] Rebates Received Data; and [] Rebates Paid Out Data".[6]

"Transaction data" concerns payments by the PBMs to pharmacies and reimbursements from the PBMs' clients (commonly known as "claims data"). "Discount data" concerns discounts received, as negotiated by the PBMs with pharmacies. "Rebates received data" concerns rebates received by the PBMs from manufacturers. "Rebates paid out data" concerns rebates received by the PBMs from manufacturers and passed through to their clients.[7]

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[4] Novartis's subpoena requested seven categories of documents and data from Optum, including contracts, formularies and policies for monitoring launch dates of branded and generic medications. Through the meet and confer process, Novartis and Optum were able to reach agreement on all of Novartis's requests other than Request No. 1, which is the subject of this motion.

[5] Exforge is defined as "the product described in NDA 21-990" and generic Exforge is defined as "any product that is AB-rated to Exforge by the United States Food and Drug Administration". North Decl. Ex. A at 2.

[6] *See* North Decl. Ex. A at 4-5.

[7] *See* North Decl. Ex. A at 1-3.

Optum initially objected to Request No. 1 "in its entirety" but stated its willingness to meet and confer. North Decl. Ex. B at 6. Following negotiations, Novartis agreed to narrow the time period of its request for claims data from January 1, 2007 through December 31, 2017 to January 1, 2012 to December 31, 2017. North Decl. Ex. C. Novartis also agreed to drop an additional request in the subpoena for claims and rebate data concerning medications in the same therapeutic class as Exforge and generic Exforge. *Id.* Optum ultimately agreed to produce, for the narrowed time period and specifically for Exforge and generic Exforge, its claims data, including its net payments made to pharmacies, and its rebates paid out data. *Id.* On April 1, 2020, Optum produced some, but not all, of the claims data and the rebate data that it had agreed to produce.

Optum's April 1 claims data production was deficient in two ways. *First*, Optum's claims data production did not include payments to and discounts from pharmacies, despite Optum's earlier agreement to produce that information. North Decl. Ex. C; North Decl. Ex. E. Optum refused to supplement its production with this data even after Novartis identified the issue and asked Optum to correct it. North Decl. Ex. E. To date, Optum has not provided an explanation for its refusal to provide claims data for its transactions with pharmacies.

Second, the claims data was also deficient because Optum only produced claims data for branded Exforge that was manufactured by Novartis and for generic Exforge that was manufactured by Par; it did not include any claims data for generic Exforge sold by other manufacturers despite the subpoena's clear request for information concerning purchases of all generic versions of Exforge. Optum claims that it limited its production in this manner in response to its request that Novartis provide the National Drug Codes ("NDCs")[8] associated with Novartis's branded Exforge products and generic Exforge

[8] National Drug Codes ("NDCs") are unique 10-digit product identification numbers assigned to all prescription medications in the US. Novartis provided Optum the NDCs

products (to aid in Optum's data collection). North Decl. Ex. G. Novartis provided NDCs corresponding to its branded Exforge products and Par's generic Exforge products. However, once Novartis's counsel realized there had been a miscommunication regarding the NDCs, Novartis's counsel provided Optum with a full list of NDCs and asked it to supplement its production consistent with the scope of the subpoena. North Decl. Ex. F. Optum refused. North Decl. Ex. G.

Optum's April 1 production of rebates paid out data was also deficient. It only included data for certain clients for which Optum asserted the ability to disaggregate the rebate data by medication; in other words, Optum did not produce rebate data for any rebates that it paid out to clients for whom the disbursements are not calculated on an individual product basis. Novartis identified this deficiency and requested that Optum supplement its production to provide all of the subpoenaed rebate data that Optum agreed to produce in response to Request No. 1. North Decl. Ex. H. Optum refused. North Decl. Ex. I.

In the spirit of compromise, Novartis proposed that Optum sign a declaration regarding its rebate data in exchange for which Optum would provide the claims data for the remaining generic Exforge NDCs. While the parties attempted for months to negotiate the terms of such a declaration, they were ultimately unable to reach agreement.

For the reasons set forth below, Novartis's motion should be granted and Optum should be compelled to produce the requested claims data and rebate data.

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as a courtesy, but they are publicly available on the FDA's website. *See National Drug Code Directory*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm.

III. LEGAL STANDARD

The same broad discovery parameters "set forth in Rule 26 also apply to subpoenas served upon non-parties" like Optum. *Citizens Union of City of N.Y. v. Att'y General of N.Y.*, 269 F. Supp. 3d 124, 139 (S.D.N.Y. 2017). Novartis is thus entitled to discovery from Optum concerning "any non-privileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1); *see also* ECF No. 253 (ordering production of relevant third party documents). Relevance is "construed broadly to encompass any matter that bears on, or that reasonably could lead to other matter that could bear on any party's claim or defense." *CBF Industria de Gusa S/A v. AMCI Holdings, Inc.*, 13-CV-2581 (PKC)(JLC), 2019 WL 3334503, at *5 (S.D.N.Y. July 25, 2019).

With particular relevance to this dispute, "a subpoena should not be quashed or modified where the court can devise an appropriate accommodation to protect the interests of the witness, such as a protective order or a confidentiality stipulation." *In re Salomon Bros. Treasury Litig.*, No. 91 CIV. 5471 (RPP), 1994 WL 62852, at *2 (S.D.N.Y. Feb. 22, 1994) (internal quotation marks omitted); *see also United States v. Int'l Bus. Mach. Corp.*, 83 F.R.D. 97, 99 n.6 (S.D.N.Y. 1979) (denying motion to quash subpoena in part because the existence of a protective order obviated confidentiality concerns).

IV. ARGUMENT

As noted, Novartis seeks two sets of data from Optum in this motion: (i) claims data—namely, the claims and discount data reflecting Optum's net payments to pharmacies, which Optum has withheld in their entirety, and reimbursements from

Optum's clients for all branded and generic Exforge products, regardless of their manufacturer; and (ii) Optum's rebates paid out data—namely, rebates received by Optum from manufacturers for purchases of Exforge and generic Exforge and passed through to its clients for all clients that received rebates for purchases of Exforge or generic Exforge, regardless of whether such rebates can be disaggregated by product.

A. Claims Data

Optum's claims data (including its net payments to pharmacies) for all versions of generic Exforge—including the versions of generic Exforge produced by manufacturers other than Par—are plainly relevant. The EPPs allege that the prices of *all* generic versions of Exforge (not only the version manufactured by Par) were inflated as a result of the license agreement between Novartis and Par, and purchases of those other generic versions will be factored into any damages they seek to recover in this case. There is thus no basis for Optum to withhold data relating to manufacturers other than Novartis and Par. And though Optum agreed to produce data reflecting its payments to and discounts from pharmacies during meet and confers, it inexplicably refused to include this data field when Novartis identified the deficiency in its prior productions. North Decl. Ex. C; North Decl. Ex. E.

Optum's resistance to producing its claims data for all versions of generic Exforge appears to be based in large part on the fact that Novartis provided Optum with a non-exhaustive list of NDCs to facilitate its data pull. Optum's argument is meritless. Request No. 1 seeks transaction data related to Optum's claims associated with "generic Exforge," which is defined in the subpoena to mean "*any* product that is AB-rated to Exforge by the United States Food and Drug Administration." North Decl. Ex. A (emphasis added). By providing Optum with a non-exhaustive list of NDCs, Novartis did not retroactively limit the clear and express scope of the subpoena, to which Optum agreed more than ten months ago. In fact, when Novartis realized there had been a miscommunication between it and Optum regarding the NDCs Optum expected it to

provide, Novartis promptly corrected its error by providing Optum with an exhaustive list of NDCs for all of the generic Exforge products identified in its subpoena. North Decl. Ex. F.

Optum's only other basis for refusing to produce the claims data set is a broad, unspecified burden objection. North Decl. Ex. G. It likewise falls flat. To prevail on a burden objection, Optum must demonstrate an undue burden associated with the production. *Kirschner v. Klemons*, No. 99 Civ. 4828 (RCC), 2005 WL 1214330, at *2 (S.D.N.Y. May 19, 2005) ("[T]he party seeking to quash a subpoena bears a heavy burden of proof.") (internal citations omitted). No such burden exists here. *See, e.g.*, *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices and Antitrust Litig.*, No. 17-md-2785-DDC-TJJ, 2018 WL 2445098, at *3, *5-6 (D. Kan. May 31, 2018) (finding that non-party Optum had failed to demonstrate undue burden and ordering it to produce relevant data). PBMs like Optum maintain these computerized data, including claims data for the additional NDCs, in the normal course of business. Production of the data would take little more than the click of a button. Optum should be compelled to produce the data it long ago agreed to provide.

Optum has not specified why it is unwilling to produce claims data reflecting its payments to and discounts from pharmacies and should similarly be required to supplement its production with that information. Over a year ago, Novartis emailed Optum and requested that it confirm Novartis's understandings of the agreements reached during the first meet and confer. North Decl. Ex. C. One such agreement was that Optum would produce its "transaction data (which reflects Pharmacy Discount Data)" for the newly negotiated time period. *Id.* Here, "transaction data" expressly included payments to and discounts from pharmacies, as it was defined in Novartis's subpoena to include payments by [Optum] "to the pharmacy (reflecting any discounts provided by the pharmacy to [Optum] after the point of sale)." North Decl. Ex. A. at 3. Optum did not challenge Novartis's understanding of the fields of claims data it expected Optum to

produce. North Decl. Ex. D. Only after Novartis identified the deficiencies in its production did Optum claim that it never agreed to produce claims data fields showing its transactions with pharmacies. North Decl. Ex. E. To date, Optum has not provided an explanation for its change in position or its refusal to provide data fields for its transactions with pharmacies. Production of these claim data fields should not pose an undue burden on Optum, as they too can be produced through a simple computer query.

B. Rebates Paid Out Data

Like the requested claims data, the requested rebates paid out data are plainly relevant. Because PBMs like Optum pass on manufacturer rebates to their end-payor clients, the effective prices that those end-payors paid for Exforge and generic Exforge—and here, purport to claim as damages—were directly affected by such rebates. These rebate data also bear on class certification. Optum guarantees many of its clients a certain level of rebates. When Optum is unable to secure those rebates for its clients, Optum—not its end-payor clients—bears the losses. Thus, some or all of the alleged overcharges on Exforge may have been borne by Optum, not the EPPs.[9] All rebates attributable to Exforge, including both Exforge and generic Exforge specific and aggregated rebate amounts are relevant for these reasons.

Optum insists that Novartis's demand for rebates paid out data, reflecting rebates Optum paid out on an aggregated basis, amounts to an "expanded request." North Decl. Ex. I. But Optum imposes an unreasonable reading of the subpoena. The subpoena

[9] The EPPs are attuned to this possibility and they have attempted to deal with it by excluding ***all*** PBMs, including Optum, from their class definition. *See* ECF No. 40 at 47. Even if that could be achieved consistent with Fed. R. Civ. P. 23, the question would remain how to accurately exclude any alleged injury borne by PBMs from the class damages model. The subpoenaed data would be equally necessary for that inquiry.

Moreover, the EPPs have tried to preempt an argument that Optum bore any portion of the alleged overcharges by procuring a declaration from Optum that suggests the opposite. Optum should not be allowed to lob such statements into the record but avoid the discovery needed to test their assertions.

defines "Rebates Paid Out Data" as "data concerning rebates received by [Optum] . . . and passed through to [Optum's] clients" and requires that Optum provide the "brand drug name(s) [and] generic drug name(s) covered by [the] rebate." North Decl. Ex. A. The subpoena thus covers all rebates paid out, even those that were aggregated across multiple medications. Optum, being in the business of collecting and disbursing rebates on medications, clearly is and has been aware of the issue of aggregated versus specific rebates. With full knowledge, Optum agreed to produce all the relevant rebate data. North Decl. Ex. C. Only later did Optum object to producing the aggregated rebate data. North Decl. Ex. I. Moreover, the data are aggregated only because of Optum's business practices. The fact that Optum, for its own reasons, entered into aggregated multi-product rebate deals with members of the putative EPP class should not excuse it from disclosing, in full, the amounts of any rebates pertaining to Exforge and generic Exforge.

Optum's burden objection is also unfounded. North Decl. Ex. I. Optum has already pulled rebate data for Exforge and generic Exforge to the extent they could be disaggregated. Optum has not articulated any undue burden associated with pulling the additional aggregated rebate data that Optum maintains in the ordinary course.

Nor can Optum resist production by claiming "confidentiality" over the rebate data. North Decl. Ex. I. Confidentiality alone does "not immunize . . . materials from discovery." *Grumman Aerospace Corp. v. Titanium Metals Corp. of Am.*, 91 F.R.D. 84, 87 (E.D.N.Y. 1981); *see also Conopco, Inc. v. Wein*, No. 05Civ.9899 (RCC) (THK), 2007 WL 1040676, at *5 (S.D.N.Y. Apr. 4, 2007) (a document's "confidentiality does not shield it from discovery") (internal quotation marks omitted). Several protective orders have already been entered in the underlying litigation, including protective orders requested by other subpoenaed PBMs that were promptly agreed to and ordered by the Court. *See* ECF Nos. 95, 198, 238, and 248. These orders protect against the unauthorized use or disclosure of any confidential material produced in the case,

including that produced by a "Non-Party", like Optum. Novartis has advised Optum multiple times that it would be willing to enter into another protective order to address Optum's concerns (in the event that the existing protective orders are inadequate). Optum has not meaningfully engaged with Novartis on that offer; its confidentiality objection therefore rings hollow.

V. CONCLUSION

For the foregoing reasons, Novartis respectfully requests that the Court grant its motion to compel Optum to produce data responsive to Novartis's subpoena.

December 23, 2020

Respectfully submitted,

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